State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Zimmer, Inc. – Affixus Antegrade Femoral Nailing System Products

Recall Date	Product Description	Recalling Firm	Recall Reason
12/22/2025	**Product 1** Affixus Antegrade Femoral Nails (9 mm diameter, 420 mm length, right trochanteric nail) used for intramedullary fixation of femoral fractures.	Zimmer, Inc. Warsaw, IN, USA	Affected implants may have an undersized distal shaft diameter, which could lead to implant fatigue fracture and potential complications such as pain, non-union, or need for surgical intervention.
12/22/2025	**Product 2** Affixus Antegrade Femoral Nails (9 mm diameter, 380 mm length, right trochanteric nail) used for intramedullary fixation of femoral fractures.	Zimmer, Inc. Warsaw, IN, USA	Affected implants may have an undersized distal shaft diameter, which could lead to implant fatigue fracture and potential complications such as pain, non-union, or need for surgical intervention.
12/22/2025	**Product 3** Affixus Antegrade Femoral Nails (9 mm diameter, 320 mm length, left trochanteric nail) used for intramedullary fixation of femoral fractures.	Zimmer, Inc. Warsaw, IN, USA	Affected implants may have an undersized distal shaft diameter, which could lead to implant fatigue fracture and potential complications such as pain, non-union, or need for surgical intervention.
12/22/2025	**Product 4** Affixus Antegrade Femoral Nails (9 mm diameter, 340 mm length, right trochanteric nail) used for intramedullary	Zimmer, Inc. Warsaw, IN, USA	Affected implants may have an undersized distal shaft diameter, which could lead to implant fatigue fracture and

	fixation of femoral fractures.		potential complications such as pain, non-union, or need for surgical intervention.
12/22/2025	**Product 5** Affixus Antegrade Femoral Nails (9 mm diameter, 280 mm length, left piriformis nail) used for intramedullary fixation of femoral fractures.	Zimmer, Inc. Warsaw, IN, USA	Affected implants may have an undersized distal shaft diameter, which could lead to implant fatigue fracture and potential complications such as pain, non-union, or need for surgical intervention.
12/22/2025	**Product 6** Affixus Antegrade Femoral Nails (9 mm diameter, 300 mm length, left trochanteric nail) used for intramedullary fixation of femoral fractures.	Zimmer, Inc. Warsaw, IN, USA	Affected implants may have an undersized distal shaft diameter, which could lead to implant fatigue fracture and potential complications such as pain, non-union, or need for surgical intervention.
12/22/2025	**Product 7** Affixus Antegrade Femoral Nails (9 mm diameter, 400 mm length, right trochanteric nail) used for intramedullary fixation of femoral fractures.	Zimmer, Inc. Warsaw, IN, USA	Affected implants may have an undersized distal shaft diameter, which could lead to implant fatigue fracture and potential complications such as pain, non-union, or need for surgical intervention.
12/22/2025	**Product 8** Affixus Antegrade Femoral Nails (9 mm diameter, 360 mm length, right trochanteric nail) used for intramedullary fixation of femoral fractures.	Zimmer, Inc. Warsaw, IN, USA	Affected implants may have an undersized distal shaft diameter, which could lead to implant fatigue fracture and potential complications such as pain, non-union, or need for surgical intervention.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Product 1** **Model No.:** 815509420 **UDI-DI:** (01)00887868143571(17)340920(10)66717556 (01)00887868143571(17)340920(10)66884566 **Lot Number**: 66717556, 66884566 **S/N range:** N/A	22 Units Nationwide including California	December 2025 and prior
II	**Product 2** **Model No**.: 815509380 **UDI-DI**: (01)00887868143557(17)340822(10)66717554 (01)00887868143557(17)340822(10)66884564 (01)00887868143557(17)350421(10)67042197 **Lot Number**: 66717554, 66884564, 67042197 **S/N range:** N/A	23 Units Nationwide including California	December 2025 and prior
II	**Product 3** **Model No**.: 815609320 **UDI-DI**: (01)00887868144479(17)340826(10)66717601 (01)00887868144479(17)340820(10)66892900 **Lot Number**: 66717601, 66892900 **S/N range:** N/A	23 Units Nationwide including California	December 2025 and prior
II	**Product 4** **Model No**.: 815509340 **UDI-DI**: (01)00887868143533(17)340822(10)66717552 (01)00887868143533(17)340826(10)66884562 **Lot Number**: 66717552, 66884562 **S/N range:** N/A	22 Units Nationwide including California	December 2025 and prior

II	**Product 5** **Model No**.: 815809280 **UDI-DI**: (01)00887868584763(17)350416 (10)67066287 **Lot Number**: 67066287 **S/N range:** N/A	3 Units Nationwide including California	December 2025 and prior
II	**Product 6** **Model No**.: 815609300 **UDI-DI**: (01)00887868144462(17)340826 (10)66717600 **Lot Number**: 66717600 **S/N range:** N/A	11 Units Nationwide including California	December 2025 and prior
II	**Product 7** **Model No**.: 815509400 **UDI-DI**: (01)00887868143564(17)340821 (10)66717555 (01)00887868143564(17)340822 (10)66884565 (01)00887868143564(17)350801 (10)67379212 **Lot Number**: 66717555, 66884565, 67379212 **S/N range:** N/A	23 Units Nationwide including California	December 2025 and prior
II	**Product 8** **Model No**.: 815509360 **UDI-DI**: (01)00887868143540(17)340917 (10)66717553 (01)00887868143540(17)340823 (10)66884563 **Lot Number**: 66717553, 66884563 **S/N range:** N/A	22 Units Nationwide including California	December 2025 and prior

For additional information, please visit the FDA website